

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 34-40 are pending. Claims 34, 38, 39 and 40 have been amended for clarification. Support for the amendments can be found throughout the instant specification. The amendments are not to be construed as acquiescence with regard to the Action's rejections and are made without prejudice to prosecution of any subject matter removed or modified by amendment in a related divisional, continuation, or continuation-in-part application. No new matter has been added to the application.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 34-40 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Action notes several typographical errors, and also alleges the phrase "standard value" of Claim 34 is unclear.

Applicants kindly thank the Examiner for noting the typographical errors in Claims 34, 38, 39 and 40 and submit the errors have been corrected in the amended claims.

With regard to the rejection of Claim 34 as allegedly being indefinite, Applicants respectfully traverse this ground for rejection and submit Claim 34 particularly points out and distinctly claims the subject matter of the present invention. In particular, the Action states "standard value" of Claim 34 is unclear. Applicants submit, without acquiescing to any rejection, that Claim 34 has been amended for clarification to recite "a value that represents the number of total cells (viable and nonviable) in said sample". Applicants submit that one of ordinary skill in the art would readily appreciate the number of total cells in a sample may be determined by several standard techniques used in the art, including native UV (ultra-violet) absorption, turbidity testing, hemacytometer measurements, or fluorescence. Support for these techniques, as well as the amendment to Claim 34, may be found throughout the instant

specification, but in particular at pages 2-4 and 10-11. As such, no new matter has been added by this amendment.

Applicants submit one of ordinary skill in the art would easily ascertain the scope of amended Claim 34 such that it particularly points out and distinctly claims the subject matter which Applicants regard as their invention. Thus, Applicants submit the grounds for this rejection have been overcome and respectfully request this rejection be withdrawn.

Rejection under 35 U.S.C. §102(b); first rejection

Claims 34-38 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Breeuwer *et al.* (Applied and Env. Microbiol. 60(5): 1467-1472 (May 1994)). In particular, the Action states the cited reference teaches a method for detecting cell viability using carboxyfluorescein diacetate in combination with flow cytometry.

Applicants respectfully traverse this ground for rejection and submit the cited reference does not anticipate the claimed invention. Applicants note the Federal Circuit has held a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of CA*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants further note that, without acquiescing to any rejection but solely to expedite prosecution of the claims, independent Claim 34 has been amended for clarification. As such, Applicants submit the cited reference does not anticipate the amended Claims 34-38.

Applicants submit the presently claimed invention recites a method for quantitating viable cells compared to total cells (viable and nonviable) in a sample. Applicants note the cited reference fails to teach each and every element of the claimed invention, and in fact *does not examine total cell number* in any sample evaluated. Furthermore, the cited reference clearly states its disclosed method does not provide an accurate indication of the number of viable cells in a sample. *See* p. 1472, second paragraph, "Hence, the fluorescence intensity is not necessarily reflecting the viability (of cells) as such. The only reasonable assumptions which can be made (from the results) are that stained cells do not have severely damaged membranes and contain esterase activity." *See also* p.1470, column 2, and p. 1471,

Figure 8, for “heterogeneous results” of cell fluorescence following carboxyfluorescein treatment as disclosed by the method of the cited reference.

Thus, Applicants submit the cited reference does not contain each and every element in the present claims. As such, Applicants submit these grounds for rejection have been overcome, and respectfully request the rejection be withdrawn.

Rejection under 35 U.S.C. §102(b); second rejection

Claims 34, 36, 37, 39 and 40 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Sarkadi *et al.* (U.S. Pat. No. 6,277,655). In particular, the Action alleges Sarkadi *et al.*, disclose a method and kit for quantifying viable cells, as well as instructions for performing the same.

Applicants respectfully traverse this ground for rejection and submit the cited reference does not anticipate the claimed invention. Applicants note the Federal Circuit has held a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of CA*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants further note that, without acquiescing to any rejection but solely to expedite prosecution of the claims, independent Claim 34 has been amended for clarification. As such, Applicants submit the cited reference does not anticipate the amended claims.

Applicants submit the presently claimed invention recites a method for quantitating viable cells compared to total cells (viable and nonviable) in a sample. Applicants submit the cited reference does not teach the claimed invention but rather relates to evaluating multi-drug resistance in cells. Applicants note the Action cites several sections of the cited reference as allegedly quantifying viable cells (in particular, columns 9-11). Applicants submit the cited reference relates to using flow cytometry in conjunction with various reagents related to multi-drug resistance proteins but *does not quantify total cells (viable and nonviable)* in a sample. Applicants submit the cited reference clearly states its use of flow cytometry “permits the exclusion of non-viable cells from the analysis of MDR activity, and permits evaluation of MDR on a cell-by-cell basis.” *See* lines 1-10, column 11. Applicants submit the cited reference

evaluates particular fluorescence of a cell in relation to its transport protein ability, and *does not quantify viable cells or total cells (viable and nonviable) in a sample*. Therefore, Applicants submit each and every element of the rejected claims is not found in the cited reference. As such, Applicants respectfully submit these grounds for rejection have been overcome and request this rejection be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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